FUNCTIONALITY-RELATED CHARACTERISTICS

This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient. This section is a non-mandatory part of the monograph and it is not necessary to verify the characteristics to demonstrate compliance. Control of these characteristics can however contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.

The following characteristics may be relevant for poly(vinyl acetate) dispersion 30 per cent used in the manufacture of modified-release dosage forms and to mask taste.

Solubility of a film. Place the film obtained in identification test B in 50 ml of *phosphate buffer solution pH 6.8 R* whilst stirring continuously. The film does not dissolve within 30 min.

Apparent viscosity (*2.2.10*): maximum 100 mPa·s, determined using a rotating viscometer at 20 °C and a shear rate of 100 s^{-1}.

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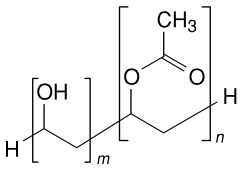
POLY(VINYL ALCOHOL)

Poly(alcohol vinylicus)



DEFINITION

Poly(vinyl alcohol) is obtained by polymerisation of vinyl acetate, followed by partial or almost complete hydrolysis of poly(vinyl acetate) in the presence of catalytic amounts of alkali or mineral acids.

Poly(vinyl alcohol) polymers comply with the following indices:

$$0 \leq \frac{n}{m} \leq 0.35$$

The mean relative molecular mass lies between 20 000 and 150 000. The viscosity is 3 to 70 mPa·s. The ester value which characterises the degree of hydrolysis is not greater than 280.

CHARACTERS

Appearance: yellowish-white powder or translucent granules.

Solubility: soluble in water, slightly soluble in ethanol, practically insoluble in acetone.

Various grades of poly(vinyl alcohol) are available. They differ in their degree of polymerisation and their degree of hydrolysis which determine the physical properties of the different grades. They are characterised by the viscosity and the ester value of the substance.

IDENTIFICATION

A. Infrared absorption spectrophotometry (*2.2.24*).

Preparation: discs; in some cases, the sample has to be milled, after cooling if necessary, before preparing the discs.

The spectrum obtained shows absorption maxima corresponding to poly(vinyl alcohol) at 2940 cm^{-1} and 2920 cm^{-1}.

B. It complies with the test for viscosity (see Tests).

TESTS

Solution S. Heat on a water-bath 250 ml of *water R* in a borosilicate round-bottomed flask attached to a reflux condenser with stirrer, add 10.0 g of the substance to be examined and continue heating for 30 min with continuous stirring. Remove the flask from the water-bath and continue stirring until room temperature is reached.

Appearance of solution. Solution S is clear (*2.2.1*) and not more intensely coloured than reference solution Y_7 (*2.2.2, Method II*).

pH (*2.2.3*): 4.5 to 6.5 for solution S.

Viscosity (*2.2.49*): 85 per cent to 115 per cent of the value stated on the label.

Determine the viscosity using a falling ball viscometer immediately after preparation of solution S at 20 ± 0.1 °C.

Acid value: maximum 3.0.

Add 1 ml of *phenolphthalein solution R* to 50 ml of solution S and titrate with *0.05 M potassium hydroxide* until the pink colour persists for 15 s. Calculate the acid value from the expression:

$$\frac{2.805V}{2}$$

V = number of millilitres of *0.05 M potassium hydroxide* used.

Ester value (*2.5.2*): 90 per cent to 110 per cent of the value stated on the label.

Saponify 1.00 g in a mixture of 25.0 ml of *0.5 M alcoholic potassium hydroxide* and 25.0 ml of *water R* (*2.5.6*).

Heavy metals (*2.4.8*): maximum 10 ppm.

1.0 g complies with limit test D. Prepare the standard using 1 ml of *lead standard solution (10 ppm Pb) R*.

Loss on drying (*2.2.32*): maximum 5.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 3 h.

Sulphated ash (*2.4.14*): maximum 1.0 per cent, determined on 1.0 g.

The following test concerning the pharmacotechnological properties may be carried out depending on the intended formulation. It is not a mandatory requirement.

Infrared absorption spectrum (*2.2.24*). The determination of the spectrum and comparison with a suitable sample is useful for ensuring suitable functionality-related properties. The intensities of the absorption maxima at 1720 cm^{-1} and 1260 cm^{-1} are inversely proportional to the degree of hydrolysis.

LABELLING

The label states:

– the viscosity for a 40 g/l solution,

– the ester value.